

Rx News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bndd/index.php

What Can a Pharmacist Change on a Prescription?

On April 19th, 2010, the United States Drug Enforcement Administration (DEA) stated that while the DEA was reviewing their current federal regulation, they would allow pharmacists to make changes to controlled substance prescriptions according to the laws and policies of the individual states. The Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) and the Missouri Board of Pharmacy published the following guidelines:

How to change the prescription:

A pharmacy may change the information on a prescription only after contacting the prescriber and obtaining permission. The prescriber may send written permission or the prescriber may communicate the changes orally while the pharmacy staff is reducing the oral changes to writing. The pharmacy shall document the prescription with the date, changes, and the person authorizing the changes.

What may be changed/added with permission:

- Date written
- Patient's address
- Drug form
- Drug strength
- Quantity to be dispensed
- Prescriber's DEA number
- Directions for use
- Whether substitutions are permitted
- Refill information
- Medical reasons for extended supplies of Schedule II drugs



REMINDER:

The patient name, the drug name, the prescriber's name and the prescriber's signature can never be changed.

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DEA Instructs Pharmacies NOT To Pre-Populate

Federal regulation 21 CFR 1306.05(f) dictates that the authority to prescribe rests upon the registered practitioner. The prescriber has the primary responsibility of preparing the prescription and insuring that it conforms and meets all requirements for what must be documented on a controlled substance prescription.

A pharmacist does not have the authority to prescribe a controlled substance. A pharmacist is not an “agent of the prescriber” and cannot assist in preparing the prescription. The pharmacy has their own separate registration and the pharmacist has a separate and secondary responsibility for what is required before dispensing based on a prescription. Pharmacists are only authorized to dispense controlled substances and should not become involved in the act of prescribing.

Pharmacies may call, write, or email a practitioner and inform them that a prescription is being requested. That should be the extent of the communication. The pharmacy should not perform any action that is part of preparing the prescription form, or pre-populating information that is required such as the patient’s address, doctor’s name, address, DEA number, or the drug name, strength, form or quantity.

What Has to be Printed on a Prescription Form?

The bureau receives many telephone calls from practitioners who are attempting to print their own prescription pads. If a prescription form does not meet all of the requirements, a pharmacy may refuse to dispense prescriptions. The laws governing what must be documented on the form come from multiple state and federal agencies. After reviewing state and federal controlled substance laws and the laws from the Missouri Board of Pharmacy, the Veterinary practice act, and the Center for Medicare/Medicaid (CMS), here is a list of what is required to be documented on the prescription form:

- Prescriber’s name, full practice address, telephone number, and DEA number;
- Patient’s name and full address;
- Name of the animal, and species, and animal owner if the prescriber is a veterinarian;
- The date the prescription was written and signed;
- Drug name;
- Drug strength;
- Drug form;
- Quantity to be dispensed;
- Directions for administration of the medication;
- Number of refills authorized if any;
- Signature of the prescriber; (ink required if controlled substance)
- If the prescriber does not want the prescription filled until a specific date, the prescriber may write, “Do not fill until (date)”, near the bottom of the prescription;
- The prescription form shall have two signature lines at the bottom, on opposite ends. Under the line on the right side shall be clearly printed the words, “Dispense as Written.” Under the line on the left side of the form shall be clearly printed the words, “Substitution Permitted.”
- Security Paper: If the state or federal government is going to reimburse the prescriber or pharmacy for the prescription, the prescription shall be written on tamper proof security paper as required by the U.S. Department of Health and Human Services’ Center for Medicare/Medicaid Services or its successor agency. Prescriptions that are not to be reimbursed by the state or federal government shall not be required to use the tamper proof security paper.

E-KITS in Long Term Care Facilities

Missouri's regulation on how controlled substances are handled in long term care facilities (LTCF) emergency kits.

1. The DEA does not register or regulate emergency kits for LTCFs. This is left up to each individual state. The federal government requested certain criteria.
2. The state of Missouri has State Regulation 19 CSR 30-1.052 that meets all of the criteria requested by the federal government.
3. LTCFs may receive and stock controlled substances without federal DEA registrations and without the use of DEA Form 222 Official Order Forms.
4. LTCFs will be able to obtain their own Missouri BNDD controlled substances registration to stock drugs. The LTCF will hold the registration and will also be held accountable for all security and record keeping.
5. The LTCFs may receive their drug stock from a pharmacy, hospital, or physician.
6. The LTCF must have policies and procedures to govern who may access the kit and under what circumstances.
7. Medications may only be administered based upon an order from an authorized practitioner.

(This would be an "order" as defined in law for direct administration to a patient, and this does not include a prescription.)

19 CSR 30-1.052 Records for Long-Term Care Facilities (LTCF)

- (1) Long-term care facilities (LTCFs) and their suppliers shall maintain written records of transfers of controlled substances from the supplier to the LTCF emergency kit.
- (2) The records shall include the date of transfer; the name of each controlled substance, the strength, dosage form and quantity; the name, address and controlled substance registration number of the supplier and the name, address and controlled substance registration number of the LTCF. Federal Drug Enforcement Administration (DEA) official order forms shall not be used to record transfers of controlled substances to LTCF emergency kits. (Since LTCFs do not have DEA numbers and forms.)
- (3) No physician's order or prescription shall be used for initial stocking or replacement of controlled substances in the emergency kit. Controlled substances contained in the kit shall be obtained from a pharmacy, hospital or practitioner who holds a controlled substances registration.
- (4) The administration and medical staff of the LTCF, in conjunction with the primary supplier, shall designate in written protocols and procedures who may have access to the emergency kit, who may administer controlled substances from the emergency kit and under what circumstances and a list of the controlled substances it intends to maintain in the emergency kit. These protocols and procedures shall be subject to review and approval by the Department of Health. Only those individuals designated in the LTCF's written policies and procedures shall have access to or administer controlled substances from the emergency kit.
- (5) Each administration of controlled substances from the emergency kit shall be based upon a practitioner's order and shall be recorded in an administration record separate from the patient's medical record. This administration record shall include: the date, patient's name, drug name, drug strength, dosage, ordering practitioner's name and name of the person administering the controlled substance.

(Administrations are based on an "order" and not a prescription.)

(Both the Missouri regulation and the federal regulations define "order" as "an order for medication that is dispensed to a patient for immediate administration to the ultimate user, for example an order to dispense a drug to a bed patient for immediate administration—this is not a prescription. A prescription is dispensed by a pharmacist from a retail pharmacy and provides the patient with a supply of drugs for future use. The definition of "prescription" does not include an order that is given for immediate administration to the patient.)



Questions

Regarding Electronic Prescribing

The Bureau of Narcotics and Dangerous Drugs is working at the state level to have the Missouri regulations match the federal DEA regulations. Registrants may participate in electronic prescribing as long as they follow the federal guidelines set forth in Federal Regulations 21 CFR Part 1311.

More information can be found on the DEA's Frequently Asked Questions at:

www.deadiversion.usdoj.gov/ecommm/e_rx/index.html.

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